

Revised April 28, 1997

MAY 16 1997

510(k) Summary

K971124

**1.0 Date Prepared**

March 24, 1997

**2.0 Submitter (Contact)**

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**3.0 Device Name**

Proprietary Name: TM Micro-Catheter

Common Name: Catheter

Classification Name: Percutaneous Catheter

**5.0 Device Classification**

Xomed believes TM Micro-Catheters to be unclassified and review by the ENT Devices branch is suitable for the intended use. The TM Micro-Catheter is similar to a Tympanostomy Tube; 21CFR 874.3880 which is intended to be implanted into the tympanic membrane.

**6.0 Device Description**

The TM Micro-Catheters are formed of silicone elastomer tubing. Connected to the tubing at the proximal end is an injection port. The TM Micro-Catheter w/ Flange (In-dwelling style) has a small distal flange end for retention in the eardrum. The TM Micro-Catheter w/o Flange has a distal end with a bevel.

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**7.0 Intended Use**

The TM Micro-Catheter w/ Flange is intended for use as a temporary (less than 29 days) indwelling catheter for delivery of fluids in the treatment of patients with ear disorders. The TM Micro-Catheter w/o Flange is indicated for the immediate (up to 4 hours) delivery of fluids into the middle ear in treating ear disorders.

**8.0 Substantial Equivalence**

The TM Micro-Catheter with Flange and TM Micro-Catheter without Flange described in this notification have the same intended use as the predicate Microtek Irrigation system (K844061) for delivery of fluids into the middle ear. TM Micro-Catheters have the technological characteristics of the predicate tympanostomy tubes and butterfly catheters (K820453 or K810461) and so do not raise any new issues of safety or effectiveness.